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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 08/950,963 | 10/15/1997 | JOEL A. DREWES | 074022-3302 | 9997 |

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EXAMINER

MARSCHER, ARDIN H

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1631

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/950,963

Applicant(s)

DREWES ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 18-34 and 36-50 is/are pending in the application.
- 4a) Of the above claim(s) 13-17 and 35 have been canceled is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 18-34, and 36-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/12/03 has been entered.

Applicants' arguments, filed 9/12/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

PRIOR ART

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 5, 6, 9, 18-20, 22-24, 26, and 36 rejected under 35 U.S.C. 103(a) as being unpatentable over Oberhardt (P/N 4,849,340).

This rejection is reiterated and maintained from the previous office action, mailed 6/24/03. Applicants argue that the reference does not describe an optically functional layer which changes an optical property upon a change in mass related to analyte binding as the present claims recite. Applicants detail this argument by stating that the optical property in Oberhardt is changed in color upon binding of antibody-enzyme conjugates and substrate. This argument admits of binding of biomolecules such as the recited conjugates and substrate. These biomolecules are not massless but rather do, in fact, have mass thus still meeting this optical layer function as instantly claimed. It is additionally noted that the instant claims cite the change in optical property due to mass is "related" to analyte binding. Thus, a series of binding reactions, started by analyte binding per se is reasonably interpreted as being "related" as required in the instant claims. Therefore, this argument of applicants is non-persuasive.

Claims 1-7, 18, 19, 21, 23, 25, 26, 36, and 38-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al. (P/N 6,023,540).

This rejection is reiterated and maintained from the previous office action, mailed 6/24/03. Applicants argue that the reference that the Walt et al. patent does not disclose a device as recited in the present claims and that specifically that continuous channels through each of the various layers are not disclosed in said reference. In response the flow of liquid through the layers wherein optical function, attachment, and analyte specificity, and support has been previously described in detail in the previous

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office action, mailed 5/6/02. All of said layers with the support are exposed to the sample solution thus indicating that liquid flow channels are present to permit such flow, albeit the channels being microscopic in nature and nonlinear in layout. It is noted that the above rejected claims lack any limitation as to the linearity of the channels or their size, therefore being inclusive of a device wherein the channels are continuous, but microscopic and nonlinear. This argument is therefore non-persuasive. Applicants further argue that the wells at the terminal ends of the optical fiber bundle are not continuous with any other channels. In response applicants seem to be equating linearly lined up with continuous. Such linear lining up of channels is not an instant claim limitation. Channels therefore which vary in size, orientation, cross-section, etc. as is acknowledged are present in the Walt et al. devices are deemed to be within the scope of the instant claims as there is liquid flow which reaches all layers of the Walt et al. devices therefore getting there via channels. In order for a liquid to enter a device for analyte binding etc. a path of flow, or channel, or some type must be present. This argument is therefore non-persuasive. Applicants then argue that the instant claims recite configuration of the claimed devices for laminar flow which is not described in Walt et al. In response as set forth in the previous 2 office actions, limitations directed to use of the instantly claimed device is directed to a process and does not specify what specific device physical shape etc. would result in configuration so that laminar flow is produced. As such a device such as in Walt et al. appears to be useful in simple calm sample analysis with flows that may vary widely including laminar flow as well as others. There is no indication that turbulence is required in the Walt et al. device use thus

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leaving clearly available sample methodology which is commonly slow in nature and non-turbulent such as would occur in laminar flow. It was also set forth in the previous office action, mailed 5/6/02, that legal decisions as repeated below support this rejection and shift the burden to applicants to define specific physical characteristics of the instantly claimed devices which differ from the prior art devices as in Walt et al. It is noted that applicants have not done so in arguments regarding this rejection.

Therefore, the normal and common slow and calm sample analysis procedures as are utilized with assay devices are fully expected to be usable with laminar flow in the Walt et al. devices. Applicants argue that diamond-like and non-specific capture limitations are not present in Walt et al. This argument is an allegation without factual basis and therefore non-persuasive, especially considering that diamond-like carbon-carbon bonds were set forth previously in the office action, mailed 5/6/02, and not argued as to what distinguishes the instant diamond-like character from that of the reference, nor what is specific as to analyte capture for such carbon-carbon structures in Walt et al. which have no analyte specificity description associated therewith. Lastly, applicants requested specific and clear pointing to elements of the instant claims as found in the reference. In response, the rejection based on Walt et al. has been detailed originally in the office action, mailed 5/6/02, as well as reiterated in the most recent action, mailed 6/24/03, and is herein referred to as basis for each element of the claimed devices in the reference. It is noted that any specific arguments have been responded to above as being non-persuasive, as well as arguments regarding previous office action.

OBVIOUSNESS-TYPE DOUBLE PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 5-12, 23, 24, 26-34, and 36-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 51, 52, 54, 55, 57-63, 66-68, 70, 71, 73-79, and 82 of copending Application No. 09/675,518. This rejection is reiterated and maintained from the previous office action, mailed 6/24/03. Applicants have not argued this rejection which is therefore still deemed to be proper.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61

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(November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)).
The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

December 12, 2003


ARDIN H. MARSCHEL
PH.D.